

REQUIRED OUTCOMES REPORTING TO SCTOD BEGINS THIS MONTH

Beginning this month, hematopoietic cell transplant centers must report treatment outcomes for all related and unrelated allogeneic blood and marrow transplants, if the donor or recipient is in the United States. The Center for International Blood and Marrow Transplant Research (CIBMTR) data collection forms and electronic systems have been revised to accommodate the federally mandated requirements.

Transplant centers have been informed about the inauguration of a Stem Cell Therapeutic Outcomes Database (SCTOD) required by the C. W. Bill Young Transplant Program, which was enacted in December 2005. The CIBMTR has been awarded the federal contract to maintain the SCTOD and, in collaboration with the National Marrow Donor Program (NMDP), has expanded its data collection forms to include the necessary data. The TED (Transplant Essential Data) forms have been revised in collaboration with the European Group for Blood and Marrow Transplantation. The database will be used for evaluation of the program's operations, including federally required research such as analyses of transplant center-specific outcomes and optimal registry/cord blood bank size.

"The CIBMTR will continue to collect data for scientific research, both at the TED level and comprehensive research report forms on a subset of allogeneic and autologous transplants," said Mary Horowitz, MD, MS, chief scientific director of the CIBMTR. "Although these activities are not part of the SCTOD, we have taken advantage of the many changes required to implement the SCTOD to make some additional changes that we think will significantly enhance our research program and assist centers who participate in that program."

The CIBMTR and NMDP have harmonized their respective Research Report Forms into a single set of forms. The

CIBMTR and NMDP also have developed an overall data management plan that includes electronic data submission of the TED forms and the harmonized research forms, a combined audit program, and combined data submission policies and procedures. Centers will no longer submit data to both the NMDP and CIBMTR. Each center is receiving a packet of information that provides further details about the SCTOD and how it impacts their center. Included in the packet will be sample copies of the TED forms and the harmonized research forms.

ASBMT COMMENTS ON MEDICARE PAYMENTS FOR CLINICAL TRIALS

A revision of federal policies on reimbursement of treatment for Medicare patients in clinical trials has been proposed by the Centers for Medicare and Medicaid Services (CMS). ASBMT, together with the National Marrow Donor Program, has submitted comments.

The current reimbursement policy, in effect since 2000, has Medicare paying for patient care services within clinical trials that otherwise would be reimbursed outside of clinical trials. This overall policy would not change under the proposed new rules, but there would be a variety of additional requirements.

The comments submitted by ASBMT offered general support for the revisions, but raised several concerns about an exclusion from studies of Medicare participants younger than 65, an exclusion of self certification and IND-exempt studies, requirements for the publication of flawed studies or the premature results of studies, and the absence of a provision to "grandfather" patients currently enrolled in clinical trials.

CMS is expected to publish its final rules by July 9.

CONFERENCE READIES CENTERS FOR RADIATION EMERGENCIES

A one-day conference will address ways that BMT centers and personnel

can prepare for radiation/nuclear emergencies. To be held Sept. 25 in Bethesda, Md., the conference is being organized by the Radiation Injury Treatment Network (RITN), a cooperative effort of the National Marrow Donor Program and ASBMT.

The conference will provide an overview of the impact and medical challenges that would arise after a radiological accident or the detonation of a nuclear bomb within the United States borders. Presentations will include assessments of the current threat and a review of possible scenarios. In-depth information on the medical complications of acute radiation syndrome and its impact on vital organs will be discussed.

Speakers will include Brooke Budemeier; Nelson Chao, MD; C. Norman Coleman, MD; Theodor Fliedner, MD; Martin Hauer-Jensen, MD; Viktor Meineke, MD; Michael Robbins, PhD; and Alla Shapiro, MD.

The conference hours will be 8:30 a.m. to 5:00 p.m. at the Marriott Bethesda Hotel, 5151 Pooks Hill Road.

BLOOD STEM CELL TRANSPLANTS EXCEED 16,000 YEARLY IN U.S.

Currently more than 16,000 hematopoietic stem cell transplants are performed annually in the United States, according to estimates from the Center for International Blood and Marrow Transplant Research (CIBMTR).

Based on data submitted by participating transplant centers, the CIBMTR estimates that the numbers of transplants in 2005 were:

- Autologous – 10,000
- Related allogeneic – 3,500
- Unrelated allogeneic – 2,250
- Cord blood – 550

Detailed information about transplant indications, recipient age, graft sources, transplant regimens and outcomes can be found on the CIBMTR Web site at www.cibmtr.org.